REMARKS

I. Status of the Claims

Claims 69-92 and 94-96 have been withdrawn from consideration as drawn to non-elected species. Claims 55-65 and 67-96 are currently in the case.

II. Objection to the Specification

The Action objects to the Specification on the ground that there is a reference to the claims on page 12 and that the claims are subject to change.

Applicants do not understand this objection to the Specification. The claims are subject to change during prosecution, but any reference to the claims appearing in the specification is written to be read in an issued patent in which the claims should not change. There appears to be no reference to the claims in the present specification that would cause any ambiguity during prosecution.

Applicants request a further explanation or a withdrawal of this objection.

III. Rejections Under 35 USC §112

Claims 55-65, 67, 68 and 93 are rejected under §112, first paragraph for alleged lack of enablement for any composition other than a topical composition. Applicants believe that claim 93 was added to this rejection in error, as claim 93 is limited to a topical composition and should not have been included.

With respect to claims 55-65, 67, and 68, Applicants respectfully continue to traverse in that this rejection is based on a completely erroneous construction of the scope of claim 55, which claims nothing more than a composition of water soluble peptides, made with a known starting material and specific steps to obtain a mixture of peptides of a particular range of molecular weights. That is the full scope of the claim and there is no dispute that the specification enables one of skill to make the claimed invention.

Neither is there any dispute or controversy that the specification fully enables one of skill in the art to use the claimed composition in the manufacture and use of the claimed composition in a formulation for topical administration to a human or animal subject. Nothing more is required. The Action takes the position, however, that since only a single way to use the claimed composition is enabled, then the claimed composition is not fully enabled. Applicants respectfully traverse in that the rejection is based on several false assumptions.

When a claim is drawn to a composition, there is no legal requirement that the specification describe and/or enable every possible use for that composition.

The present enablement rejection is based on the erroneous concept that the claimed material must be used in only therapeutic formulations, and further only in topical therapeutic formulations. Although the specification describes therapeutic formulations that may be made with the claimed composition, including topical formulations, the claimed composition is in no way limited to those described formulations. The Examiner is attempting to read a limitation into the claims based on the described preferred embodiments.

In contrast to the Examiner's position, the composition could also be used as a nutritional supplement, for example. The specification states on page 10, line 3-5 that it could be administered orally. It is a well know fact that proteins and peptides are composed of amino acids, and that amino acids have nutritional value. Many protein and amino acid supplements are now commercially available. No experimentation is necessary to place the peptides in a gel capsule, for example, to be used as an oral supplement for its known nutritional value, and it's fat free and carbohydrate free! Neither would it require undue experimentation to determine whether such supplementation would have a healing effect on the lining of the GI tract. The Examiner has offered no explanation of what experimentation would be required, and why any such experimentation would be, in her opinion, "undue experimentation," merely stating that any trial

and error experimentation is "undue." Applicant submits that flipping a coin is trial and error experimentation, but is hardly undue experimentation. The Examiner is not only attempting to read a limitation into the claims, she is also imposing a requirement on the specification that has no basis in the body of patent law.

The Examiner has relied on the factual inquiries as applied in *In re Wands* 8 USPQ 2d 1400 (Fed Cir. 1988) to reach her conclusion that the claims are not enabled for the full scope of the claims. Applicant submits, however, that the criteria in Wands are not applicable to the present composition claim. For example, the question in Wands was whether the specification taught one of skill how to make the antibodies that were used in the claimed method of immunoassay to detect hepatitis B surface antigen. Nowhere do Applicants find an issue of whether all possible uses of the antibodies were enabled. In addition, in all the various later Federal Circuit cases that have cited *In re Wands*, Applicant cannot find a single one that applies the Wand factors to a composition claim to determine whether all possible uses of the composition are enabled by the Specification. If the Examiner knows of any such case, she is requested to please provide that information to Applicants.

The issue here is not whether the Specification enables all compositions to which the peptide composition can be added, but rather, the enablement of the peptide composition independent of adding it to a particular type of carrier. The Specification contains more than adequate description of how to obtain the peptide composition and also teaches how to use the composition to stimulate growth of useful cell types. Nothing more is required for enablement of the composition claims. Applicant submits, therefore, that this rejection is improper and requests that the rejection be withdrawn.

IV. Claim rejections under 35 U.S.C. §103

Applicants again submit that the cited reference neither teaches or suggests the claimed inventions. The Examiner is referred to the discussions of record in response to this same rejection in previous office actions.

The rejection is improper because the cited reference is completely missing certain elements of the claims. For example, the '183 reference does not describe any isolated fraction of keratin peptides that is produced by precipitation from aqueous solution with a water-miscible organic solvent, nor does it contain any description of the small peptides that are the subject of the present claims.

Since at least these claim elements are completely missing from the cited art, the reference cannot obviate the claims, as each element of the claims must be taught or suggested by the prior art in order to make a *prima facie* case of obviousness (MPEP 2142). This rejection is therefore improper and should be withdrawn.

Establishing *prima facie* obviousness requires a showing that each claim element is taught or suggested by the prior art. *See* In re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). Specifically, establishing *prima facie* obviousness requires a showing that some combination of objective teachings in the art and/or knowledge available to one of skill in the art would have lead that individual to arrive at the claimed invention. *See In re Fine*, 5 USPQ2d 1596,1598 (Fed. Cir. 1988). Moreover, establishing *prima facie* obviousness requires not only a showing that such a combination of prior art teachings is possible, but also that the teachings would have 1) motivated the skilled artisan to make the combination to arrive at the claimed invention, and 2) suggested to the skilled artisan a reasonable likelihood of success in making and using the claimed invention. *See In re Dow Chem. Co.*, 837 F.2d 469, 473 (Fed. Cir. 1988). Absent a showing of such motivation and suggestion, *prima facie* obviousness is not established.

See Fine, 5 USPQ2d at1598. Additionally, the teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20USPQ2d 1438 (Fed. Cir. 1991)

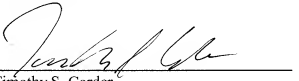
The Action appears to take the position that any peptide is equivalent to any other peptide of the same or similar molecular weight regardless of the source or the amino acid sequences. This erroneous assumption leads to the equally erroneous assumption that if one were to hydrolyze the peptide backbone of the higher molecular weight α-keratose peptides described in the '138 patent, the product would be the low molecular weight peptides of the claimed invention. Applicants do not believe this to be true, at least for the reason that the '138 peptides are isolated be acid precipitation based on the high acidic amino acid composition of the peptides. In contrast, the claimed peptides do not precipitate at low pH, but precipitate when a water-miscible organic solvent is added. One of skill in the art, therefore, would understand that the two groups of peptides have dissimilar chemical properties and hydrolyzing the larger peptides would not result in the same composition as that obtained by ethanol precipitation from the aqueous solution.

Because the '138 does not teach every element of the claims, and no expectation tht one could obtain the claimed invention by modifying the disclosure of the '138 patent, the current rejection is improper. Applicant respectfully requests that all rejections over '138 be withdrawn.

V. Conclusion

In light of the preceding discussion, all pending claims are in condition for allowance and an early indication of such is respectfully requested. Applicant further requests that the withdrawn claims be rejoined to the Application in the allowance. If the Examiner has any questions or suggestions, she is invited to call to the undersigned representative at 512.542.8446.

Respectfully submitted,



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